

## **REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 9, 11, 12 and 23-31 are in the case. Claim 10 has been canceled without prejudice.

### **I. THE INTERVIEW**

At the outset, the undersigned wishes to thank the Examiner (Mr. Singh) and his supervisor (Mr. Weber) for kindly discussing this case with the undersigned. The interview was held on December 7, 2010, and the courtesies extended by the Examiner and his supervisor were most appreciated. The substance of the interview will be clear from the Interview Summary and the comments presented below.

### **II. SPECIFICATION**

The specification has been objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 14. In response this hyperlink has been removed. Withdrawal of the objection to the specification is respectfully requested.

### **III. SEQUENCE LISTING**

The Action asserts that the application does not comply with the sequence listing rules in light of sequence disclosures at pages 2, 10, 16, 23, 27, 28, 30, 32-38, and tables 1, 2, 6 and 7. In response, sequence listing materials are submitted herewith in reply to the Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequences And/Or Amino Acid Sequence Disclosures. The specification

has been amended to include the sequence listing pages and to recite the sequence identification numbers. In accordance with 37 C.F.R. 1.821-1.825, the undersigned hereby states that the content of the paper and computer-readable copies of the sequence listing submitted in accordance with 37 C.F.R. 1.821(c) and (e), respectively, are the same. The undersigned hereby states that the submission, filed in accordance with 37 C.F.R. 1.821(g), does not introduce new matter.

#### **IV. THE OBVIOUSNESS REJECTION**

Claims 9-12 and 23-31 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Messer *et al.* (1976) (Messer) in view of Hausch *et al.* (2002) (Hausch) and Dekker *et al.* (WO 02/45 524 A2) (Dekker). The rejection is respectfully traversed.

The invention provides a method of using a proline specific endoprotease to hydrolyse at a pH of below 5.5, proline rich peptides which are brought with celiac disease, a disease associated with the occurrence of celiac disease, or a disease caused by a decreased level in a patient's body of proline specific proteases required for breakdown of these peptides. The method comprises administering a dietary supplement or a medicament comprised of the proline specific endoprotease for ingestion by a patient in need thereof, whereby the proline specific endoprotease is active in the stomach and is pepsin resistant.

As emphasized at the interview, an important aspect of the present invention is that the proline specific endoprotease ("PEP") is pepsin resistant. This feature is now recited in the claims.

During the interview, as reflected in the Interview Summary, it was indicated that if an unexpected property was demonstrated with respect to pepsin sensitivity, this would be considered in further prosecution.

In this regard, attention is directed to the reference to Stepniak *et al.*, "Highly efficient gluten degradation with a newly identified prolyl endoprotease: implications for celiac disease", Am. J. Physiol. Gastrointest. Liver Physiol. 291: G621-G629 (2006), submitted with the previous response. Stepniak shows that the present prolyl endoprotease is highly effective in the stomach compared to the prolyl endoprotease used by Hausch. Hausch uses *Flavobacterium meningosepticum* prolyl oligopeptidase which is not active in the acid pH range (see Figure 1 on page G623), but this *Flavobacterium meningosepticum* prolyl oligopeptidase is also not resistant against pepsin (see Figure 1, page G623).

It is believed this showing evidences a surprising and unexpected property relating to pepsin sensitivity as discussed during the interview. In view of this, it is believed that the invention as claimed is not suggested by Messer, Hausch and/or Dekker, whether taken singly or in any combination. Withdrawal of the obviousness rejection is respectfully requested.

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Favorable action is awaited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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